

BEST AVAILABLE COPY

DECLARATION OF INVENTORS UNDER 37 C.F.R. §1.131 Address to: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450	Attorney Docket No.	LJFE-040/LFS-149
	Confirmation No.	8555
	First Named Inventor	OUYANG, TIANMEI
	Application Number	09/988,194
	Filing Date	November 20, 2001
	Group Art Unit	1651
	Examiner Name	DAVIS, RUTH A.

Sir:

This Declaration and the attached Exhibit are being submitted in conjunction with the Applicants' Response to the Office Action dated July 26, 2004.

1. We, Tianinci Ouyang, Paing Huang and Xiaoling Zheng, declare and say that we are co-inventors of the claims of the above-captioned application.
2. As evidenced in paragraph 3 below, we conceived and reduced to practice the claimed invention prior to September 9, 2001, the publication date of EP 1 130 111 A2.
3. The claimed invention was conceived and reduced to practice prior to September 9, 2001. Evidence for conception and reduction to practice prior to September 9, 2001 is provided by an Invention Disclosure which was submitted to LifeScan, Inc. A copy of the Invention Disclosure is provided herewith as an Exhibit. The claimed invention is described in the Invention Disclosure, which Invention Disclosure specifies a date of reduction to practice of the claimed invention prior to September 9, 2001. All cited dates and text considered by the Applicants to be immaterial to conception and/or reduction to practice of the invention have been redacted.
4. We do hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001

of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Date: 11/17/04

Date: _____

Date: _____

Respectfully submitted,



Tianmei Ouyang

Paing Huang

Xiaoling Zheng

Attachment: Exhibit

F:\DOCUMENT\NLIFE\040\1.131 declaration by inventors.doc

Exhibit

PATENT MEMORANDUM

00 008 4

Date.

Example:

Table 1. Reagent for a Glucose Test Pad

Components	Quantity
Water	100 ml
(2-[-Morpholino]ethanesulfonic acid) sodium salt MES (MW 217.2, Sigma, St. Louis, MO, USA)	0.8-2.2 gm
Borax (MW 381.4, Sigma, St. Louis, MO, USA)	2-4 gm
Gantrez* 6%	20 mL
Adjust pH to 5.5-7 by adding 50% NaOH	
Triton X-305 (BASF Corporation, Moun Olive, New Jersey, USA)	0.5-2 gm
Mannitol (MW 182, Sigma, St. Louis, MO, USA)	1-10 gm
Adjust pH to 5.5-7 by adding 50% NaOH	
Sodium Nitrite (MW69, Aldirch Chemicals, Milwaukee, WI, USA)	1-5 gm
WST-5 (MW 1331.37, Dojindo)	0.8-4 gm
Phenazine Ethosulfate (PES, MW 334.4, Sigma, St. Louis, MO, USA)	100-1000 mg
Glucose Oxidase (GO, TOYOBO)	100-1000KU
Flavin Adenine Dinucleotide (FAD)	0.2-1 gm

*Gantrez AN-139 (Poly Methylvinylether-alt-Maleic Anhydride, MW 1,080,000, Cat# 41632-0, Aldrich Chemicals, Milwaukee, WI, USA) Make 6% Gantrez in water, heat to 95 C for less than 45 min. to get Gantrez 6% which is ready to use.

A 0.8 μm nylon membrane obtained from Pall was dipped into the reagent of Table I, until saturated. The excess reagent was scraped off gently with a glass rod. The resulting membrane was hung to dry in a 56°C oven for 10 minutes. Porex (0.6 mm thick) was soaked in the 5% nitrite solution and then hung to dry in a 100°C oven for ten hours. Finally, the membrane was laminated between a polyester stock (0.4 mm Melencx® polyester from ICI America, Wilmington, DE) and the nitrite-impregnated Porex.

Result:

Figure 1. With and without Borax. After stressed at 56C for 1week, Test with Hct60, 370 mg/dL Glucose.

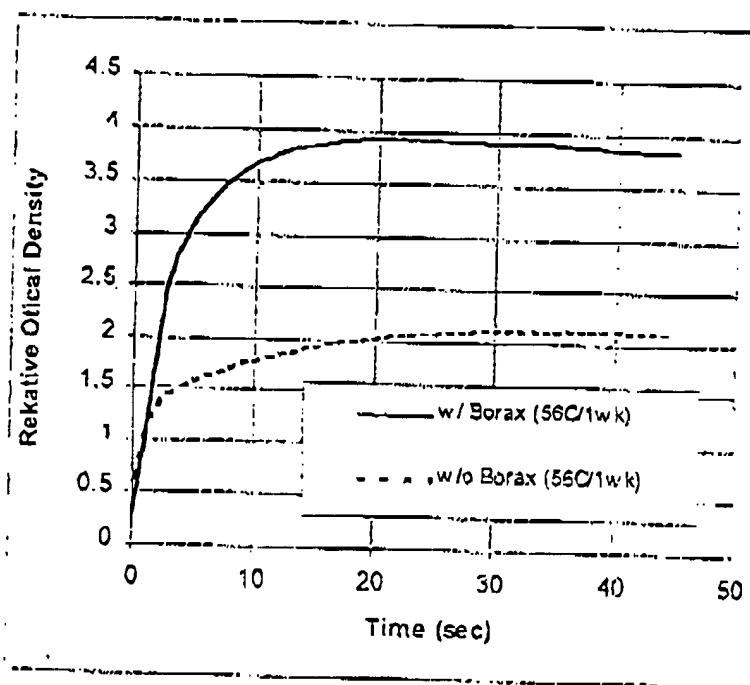


Figure 2. With and without FAD. After stressed at 56C for 1week, Test with Hct60, 370 mg/dL Glucose.

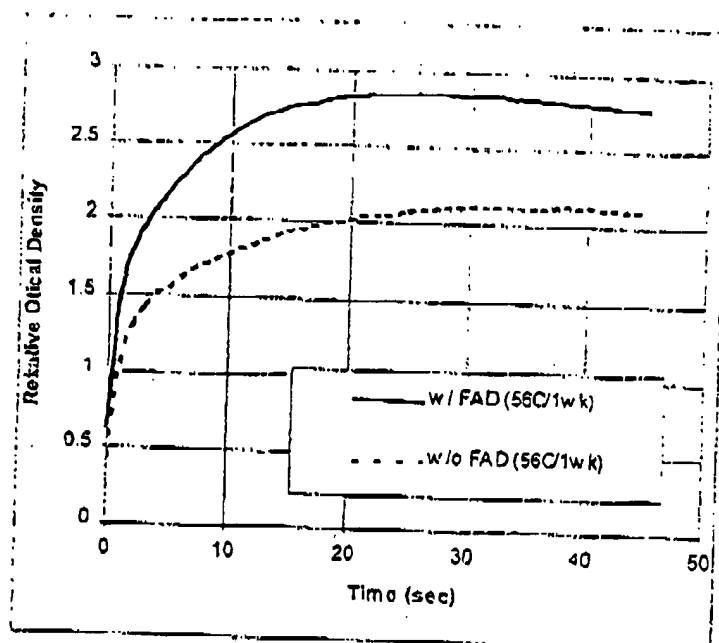
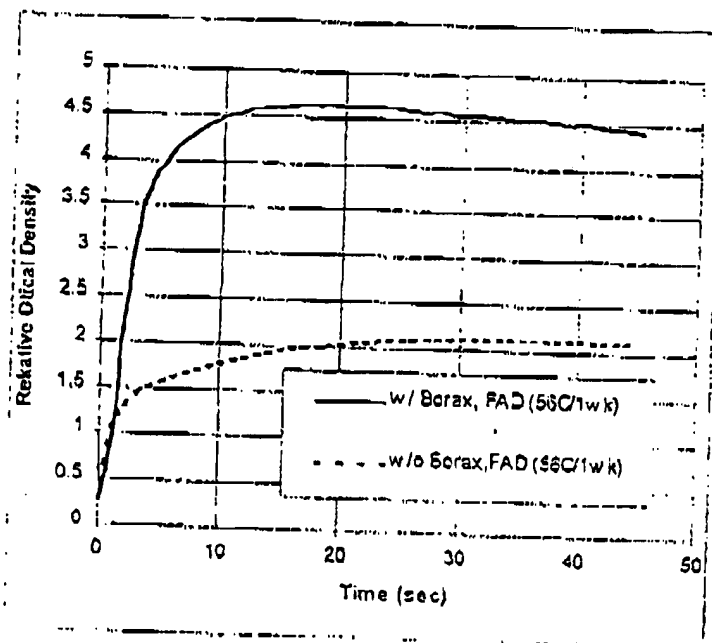


Figure 3 With and without Borax and FAD, After stressed at 56C for 1week, Test with Hct60, 370 mg/dL Glucose.



DECLARATION OF INVENTORS UNDER 37 C.F.R. §1.131 Address to: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450	Attorney Docket No.	LIFE-040/LFS-149
	Confirmation No.	8555
	First Named Inventor	OUYANG, TIANMEI
	Application Number	09/988,494
	Filing Date	November 20, 2001
	Group Art Unit	1651
	Examiner Name	DAVIS, RUTH A.

Sir:

This Declaration and the attached Exhibit are being submitted in conjunction with the Applicants' Response to the Office Action dated July 26, 2004.

1. We, Tianmei Ouyang, Paing Huang and Xiaoling Zheng, declare and say that we are co-inventors of the claims of the above-captioned application.
2. As evidenced in paragraph 3 below, we conceived and reduced to practice the claimed invention prior to September 9, 2001, the publication date of EP 1 130 111 A2.
3. The claimed invention was conceived and reduced to practice prior to September 9, 2001. Evidence for conception and reduction to practice prior to September 9, 2001 is provided by an Invention Disclosure which was submitted to LifeScan, Inc. A copy of the Invention Disclosure is provided herewith as an Exhibit. The claimed invention is described in the Invention Disclosure, which Invention Disclosure specifies a date of reduction to practice of the claimed invention prior to September 9, 2001. All cited dates and text considered by the Applicants to be immaterial to conception and/or reduction to practice of the invention have been redacted.
4. We do hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001

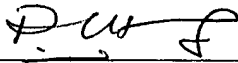
of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: _____

Tianmei Ouyang

Date: 11-17-2004


Paing Huang

Date: _____

Xiaoling Zheng

Attachment: Exhibit

F:\DOCUMENT\LIFE\040\1.131 declaration by inventors.doc

Exhibit

PATENT MEMORANDUM

00 008

4

Date.

Example:

Table 1. Reagent for a Glucose Test Pad

Components	Quantity
Water	100 ml
(2-[-Morpholino]ethanesulfonic acid) sodium salt MES (MW 217.2, Sigma, St. Louis, MO, USA)	0.8-2.2 gm
Borax (MW 381.4, Sigma, St. Louis, MO, USA)	2-4 gm
Gantrez* 6%	20 mL
Adjust pH to 5.5-7 by adding 50% NaOH	
Triton X-305 (BASF Corporation, Moun Olive, New Jersey, USA)	0.5-2 gm
Mannitol (MW 182, Sigma, St. Louis, MO, USA)	1-10 gm
Adjust pH to 5.5-7 by adding 50% NaOH	
Sodium Nitrite (MW69, Aldirch Chemicals, Milwaukee, WI, USA)	1-5 gm
WST-5 (MW 1331.37, Dojindo)	0.8-4 gm
Phenazine Ethosulfate (PES, MW 334.4, Sigma, St. Louis, MO, USA)	100-1000 mg
Glucose Oxidase (GO, TOYOBO)	100-1000KU
Flavin Adenine Dinucleotide (FAD)	0.2-1 gm

*Gantrez AN-139 (Poly Methylvinyléther-alt-Maleic Anhydride, MW 1,080,000, Cat# 41632-0, Aldrich Chemicals, Milwaukee, WI, USA) Make 6% Gantrez in water, heat to 95 C for less than 45 min. to get Gantrez 6% which is ready to use.

A 0.8 μm nylon membrane obtained from Pall was dipped into the reagent of Table 1, until saturated. The excess reagent was scraped off gently with a glass rod. The resulting membrane was hung to dry in a 56°C oven for 10 minutes. Porex (0.6 mm thick) was soaked in the 5% nitrite solution and then hung to dry in a 100°C oven for ten hours. Finally, the membrane was laminated between a polyester stock (0.4 mm Melenex® polyester from ICI America, Wilmington, DE) and the nitrite-impregnated Porex.

Result:

Figure 1. With and without Borax, After stressed at 56C for 1week, Test with Hct60, 370 mg/dL Glucose.

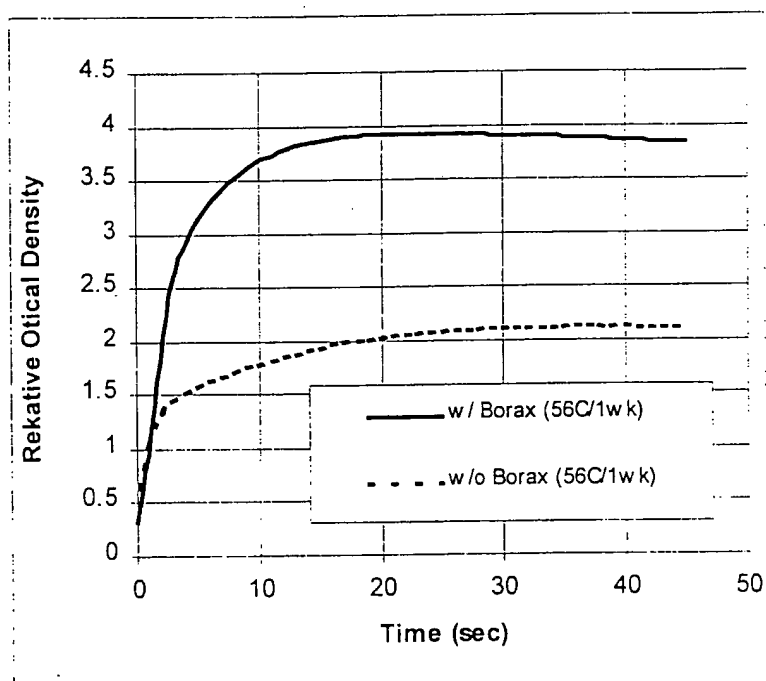


Figure 2. With and without FAD, After stressed at 56C for 1week, Test with Hct60, 370 mg/dL Glucose.

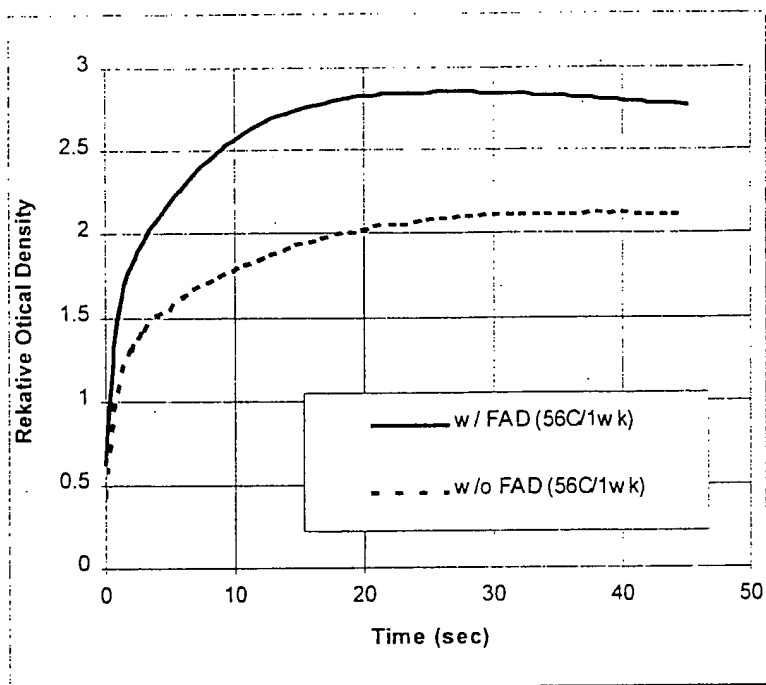
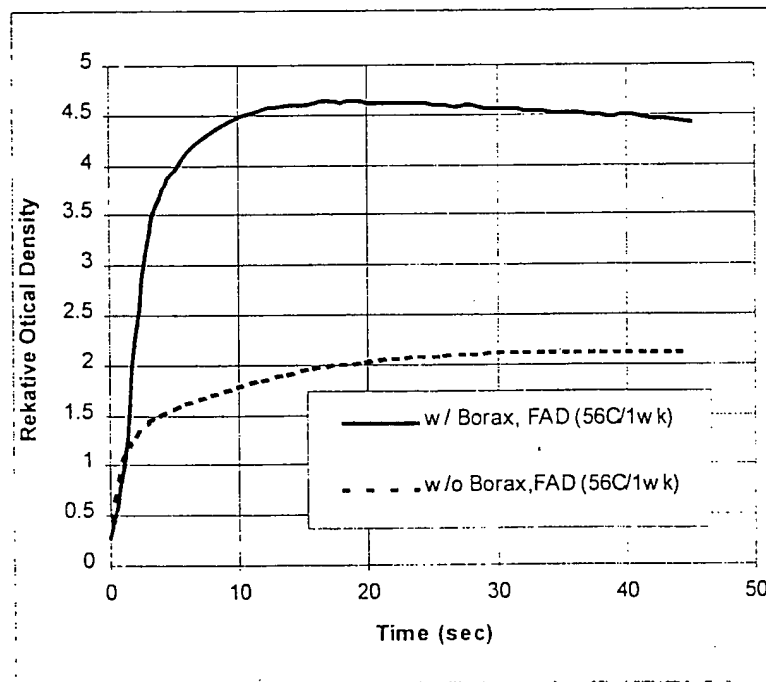


Figure 3 With and without Borax and FAD, After stressed at 56C for 1week, Test with Hct60, 370 mg/dL Glucose.



DECLARATION OF INVENTORS UNDER 37 C.F.R. §1.131 Address to: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450	Attorney Docket No.	LIFE-040/LFS-149
	Confirmation No.	8555
	First Named Inventor	OUYANG, TIANMEI
	Application Number	09/988,494
	Filing Date	November 20, 2001
	Group Art Unit	1651
	Examiner Name	DAVIS, RUTH A.

Sir:

This Declaration and the attached Exhibit are being submitted in conjunction with the Applicants' Response to the Office Action dated July 26, 2004.

1. We, Tianmei Ouyang, Paing Huang and Xiaoling Zheng, declare and say that we are co-inventors of the claims of the above-captioned application.
2. As evidenced in paragraph 3 below, we conceived and reduced to practice the claimed invention prior to September 9, 2001, the publication date of EP 1 130 111 A2.
3. The claimed invention was conceived and reduced to practice prior to September 9, 2001. Evidence for conception and reduction to practice prior to September 9, 2001 is provided by an Invention Disclosure which was submitted to LifeScan, Inc. A copy of the Invention Disclosure is provided herewith as an Exhibit. The claimed invention is described in the Invention Disclosure, which Invention Disclosure specifies a date of reduction to practice of the claimed invention prior to September 9, 2001. All cited dates and text considered by the Applicants to be immaterial to conception and/or reduction to practice of the invention have been redacted.
4. We do hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001

of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,


Date: _____

Tianmei Ouyang

Date: _____

Paing Huang

Date: 11/19/04



Xiaoling Zheng

Attachment: Exhibit

F:\DOCUMENT\LIFE\040\1.131 declaration by inventors.doc

Exhibit

PATENT MEMORANDUM

00 008

4

Date.

Example:

Table 1. Reagent for a Glucose Test Pad

Components	Quantity
Water	100 ml
(2-[-Morpholino]ethanesulfonic acid) sodium salt MES (MW 217.2, Sigma, St. Louis, MO, USA)	0.8-2.2 gm
Borax (MW 381.4, Sigma, St. Louis, MO, USA)	2-4 gm
Gantrez* 6%	20 mL
Adjust pH to 5.5-7 by adding 50% NaOH	
Triton X-305 (BASF Corporation, Moun Olive, New Jersey, USA)	0.5-2 gm
Mannitol (MW 182, Sigma, St. Louis, MO, USA)	1-10 gm
Adjust pH to 5.5-7 by adding 50% NaOH	
Sodium Nitrite (MW69, Aldirch Chemicals, Milwaukee, WI, USA)	1-5 gm
WST-5 (MW 1331.37, Dojindo)	0.8-4 gm
Phenazine Ethosulfate (PES, MW 334.4, Sigma, St. Louis, MO, USA)	100-1000 mg
Glucose Oxidase (GO, TOYOBO)	100-1000KU
Flavin Adenine Dinucleotide (FAD)	0.2-1 gm

*Gantrez AN-139 (Poly Methylvinyléther-alt-Maleic Anhydride, MW 1,080,000, Cat# 41632-0, Aldrich Chemicals, Milwaukee, WI, USA) Make 6% Gantrez in water, heat to 95 C for less than 45 min. to get Gantrez 6% which is ready to use.

A 0.8 μm nylon membrane obtained from Pall was dipped into the reagent of Table 1, until saturated. The excess reagent was scraped off gently with a glass rod. The resulting membrane was hung to dry in a 56°C oven for 10 minutes. Porex (0.6 mm thick) was soaked in the 5% nitrite solution and then hung to dry in a 100°C oven for ten hours. Finally, the membrane was laminated between a polyester stock (0.4 mm Melenex® polyester from ICI America, Wilmington, DE) and the nitrite-impregnated Porex.

Result:

Figure 1. With and without Borax, After stressed at 56C for 1week, Test with Hct60, 370 mg/dL Glucose.

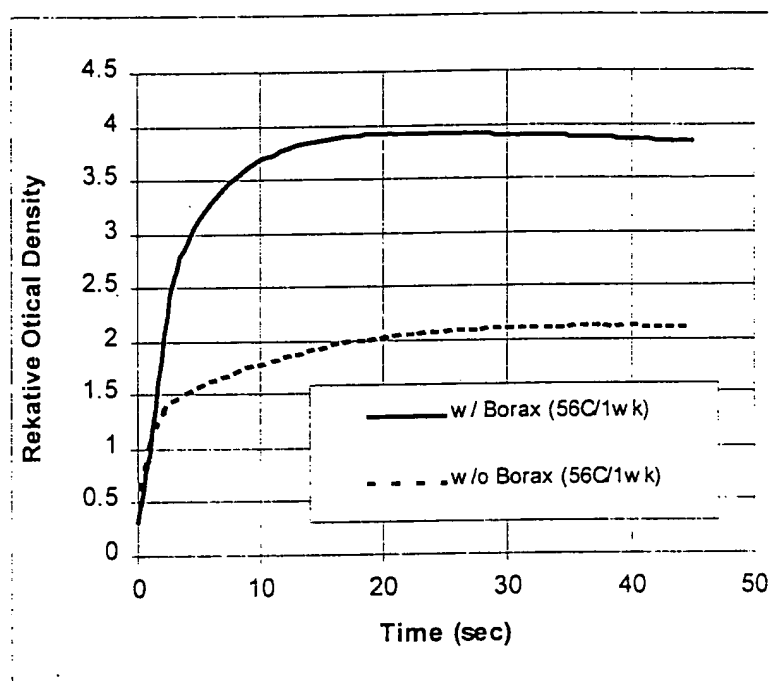


Figure 2. With and without FAD, After stressed at 56C for 1week, Test with Hct60, 370 mg/dL Glucose.

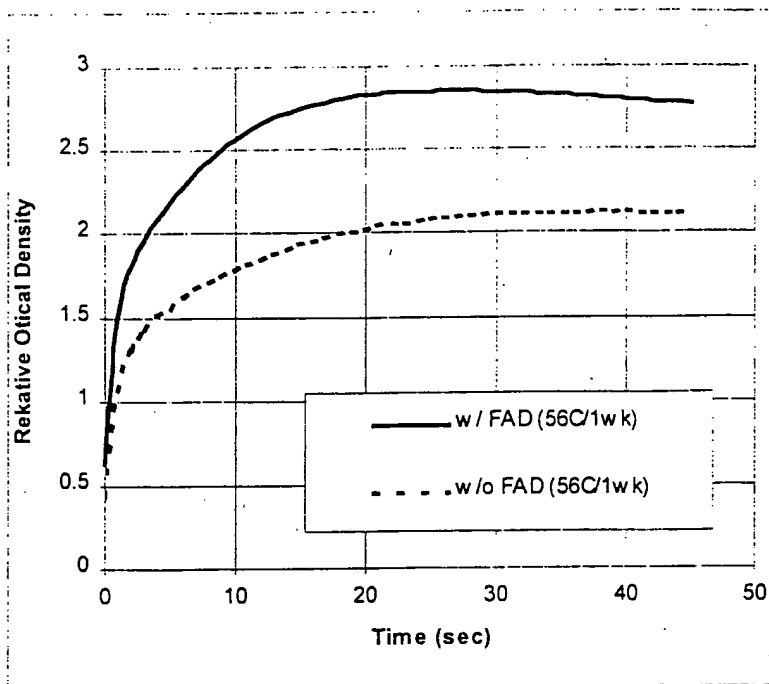


Figure 3 With and without Borax and FAD, After stressed at 56C for 1week, Test with Hct60, 370 mg/dL Glucose.

